

APR 25 2014

K140677  
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## Traditional 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92.

807.92(a)(1)

### Submitter Information

Esaote S.p.A.  
Via di Caciolle 15  
Firenze, Italy 50127

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317.228.8719  
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Date: March 17, 2014

807.92(a)(2)

### Devices

Common Name: Ultrasound Imaging System

Trade Name: 7348 Ultrasound System

Classification Name(s): Ultrasound Pulse Doppler Imaging System 892.1550  
Ultrasound Pulse Echo Imaging System 892.1560  
Transducer, Ultrasonic, Diagnostic 892.1570

Classification Number: 90IYN, 90IYO, 90ITX

807.92(a)(3)

### Predicate Device(s)

Device	Owner	510(k)
7348	Esaote	K121384
7340	Esaote	K081794, K091009, K110688

807.92(a)(4)

### **Device Description**

Model 7348 is a portable system equipped with a handle. The system size and weight allow it to be carried using its handle. The primary modes of operation are for both models: B-Mode, M-Mode, Tissue Enhancement Imaging (TEI), Multi View (MView), CW and PW Doppler, Color Flow Mapping (CFM) and Amplitude Doppler (AD). 7348 is equipped with a LCD color display where acquired images and advanced image features are shown. 7348 can drive Phased, Convex, Linear array and Doppler probes. Model 7348 has been designed to be powered by battery.

7348 has been previously cleared via k121384.

7348 Upgrade, defined herein, combine the cleared features of 7348 system with new software capabilities, listed below:

1. Managing of Tissue Velocity Mapping (TVM) and Tissue Velocity (TV) mode.
2. Managing of M-Mode with free positioning of the acquisition line (Compass M-Mode).
3. Management of Stress Echo where detection of the occurrence of stress-induced wall motion abnormalities is derived through comparison of 2D loops, displaying wall motion at rest and during and after stress.
4. Management of Intima Media Thickness to automatically measure the thickness between the intima and the media on the image in real time.

The 7348 Upgrade is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

### **Intended Use**

Esaote's Model 7348 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal, Laparoscopic and Other: Urologic. The 7348 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

807.92(a)(6)

### **Technological Characteristics**

The 7348 Upgrade employs the same fundamental technological characteristics as their predicate devices. The 7348 Upgrade model is substantially equivalent to Esaote 7348 model cleared via K121384, and to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.

- Clinical uses for which Esaote 7348 model, cleared by FDA via K121384, are designed are not changed by 7348 Upgrade, to be cleared via this submission.

- Clinical uses for which Esaote 7348 Upgrade is designed are equivalent to those of Esaote 7348 model cleared via K121384, and to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- 7348 upgrade for managing Tissue Velocity Mapping (TVM) and Tissue Velocity (TV) mode is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- 7348 upgrade for managing M-Mode with free positioning of the acquisition line (Compass M-Mode) is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- 7348 upgrade for managing Stress Echo, where detection of the occurrence of stress-induced wall motion abnormalities is derived through comparison of 2D loops, displaying wall motion at rest and during or after stress, is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- 7348 upgrade for managing Intima Media Thickness to automatically measure the thickness between the intima and the media on the image in real time, is equivalent to Esaote 7340 model cleared by FDA via K081794, K091009, K110688.
- Esaote 7348 Upgrade, 7348 and 7340 ultrasound models are designed to meet the IEC60601-1 and IEC60601-2-37 safety requirements.
- Esaote 7348 Upgrade, 7348 and 7340 ultrasound models provide an Acoustic Output Display feature per AIUM / NEMA standards, with equivalent Ispta and MI maximal values.

807.92(b)(1)

### Summary of Non-Clinical Tests

The devices have been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to conform to the following medical device safety standards.

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-2-37
- NEMA UD-3 - Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- NEMA UD-2 - Acoustic Output Measurement Standard for Diagnostic Ultrasound

807.92(b)(2)

### Summary of Clinical Tests

No clinical tests were performed.

807.92(b)(3)

### Conclusion

The 7348 Upgrade is substantially equivalent to the legally marketed devices and conform to applicable medical device safety and performance standards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

April 25, 2014

Esaote S.P.A.  
% Allison Scott  
Senior Consultant  
9001 Wesleyan Road, Suite 200  
INDIANAPOLIS IN 46268

Re: K140677

Trade/Device Name: 7348/MyLabSogno  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed Doppler imaging system  
Regulatory Class: II  
Product Code: IYN, IYO, ITX  
Dated: March 17, 2014  
Received: March 18, 2014

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the MyLabSogno, as described in your premarket notification:

Transducer Model Number

PA230  
PA122  
PA023  
LA435  
LA522  
LA523

CA123  
CA431  
2CW  
5CW  
HFCW  
EC1123

IOE323  
LP323  
TEE132  
TEE022

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

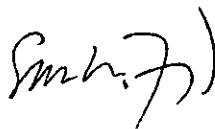
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K140677

Device Name

7348/MyLabSogno

**Indications for Use (Describe)**

Esaote's Model 7348 is a compact ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal Cardiac, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative abdominal, Laparoscopic and Other: Urologic. The 7348 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

## 7348 Upgrade

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	
Abdominal	P	P	P	P	P	P	P		P	
Intraoperative (Abdominal)	P	P	P		P	P	P		P	
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic	P	P	P	P	P	P	P		P	
Adult Cephalic	P	P	P	P	P	P	P		P	
Cardiac [2]	P	P	P	P	P	P	P	N	P	
Transesophageal (Cardiac)	P	P	P	P	P	P	P	N	P	
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	
Transvaginal	P	P	P		P	P	P		P	
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P		P	
Laparoscopic	P	P	P		P	P	P		P	
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)	P	P	P		P	P	P		P	

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CW + CFM + PD

Previously cleared via k121384

Prescription Use Only Per 21 CFR 801 Part D  
 Concurrence of CDRH

# 7348 - PA230

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PW(D)	CW(D)	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P	P	P	P	P		P	
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic	P	P	P	P	P	P	P		P	
Cardiac [2]	P	P	P	P	P	P	P	N	P	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CW + CFM + PD

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH



# 7348 - PA122

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P			
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P			
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P	N		
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P			
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CW + CFM + PD

Prescription Use Only Per 21 CFR 801  
Part D Concurrence of CDRH

# 7348 - PA023

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P	P	P	P	P			
Small Organ [1]										
Neonatal Cephalic	P	P	P	P	P	P	P			
Adult Cephalic										
Cardiac [2]	P	P	P	P	P	P	P			
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P	P	P	P	P			
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CW + CFM + PI

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH

# 7348 - LA435

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	IWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P			
Small Organ [1]	P	P	P		P	P	P			
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P			
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P			
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P			
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k132231

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + IWD + CFM + PD

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH

# 7348 - LA522

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows.

Clinical Application	Mode of Operations									
	B	M	PW	CFM	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E  
Previously cleared via k121344

- [1] Small Organs includes Breast, Thyroid and Testicles  
[2] Cardiac is Adult and Pediatric  
[3] Combined modes are: B + M + PW + CFM + PD

Prescription Use Only Per 21 CFR 801  
Part D Concurrence of CDRH

# 7348 - LA523

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transarterial										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k132466

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CFM + PD

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH

# 7348 - CA123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]	P	P	P		P	P	P		P	
Neonatal Cephalic	P	P	P		P	P	P		P	
Adult Cephalic										
Cardiac [2]	P	P	P		P	P	P		P	
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

Prescription Use Only Per 21 CFR 801  
Part D Concurrence of CDRH

# 7348 - CA431

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	
Abdominal	P	P	P		P	P	P		P	
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P		P	
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P		P	
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P		P	
Other (Urological)	P	P	P		P	P	P		P	

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E.

Previously cleared via k121384

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CFM + PD

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH

# 7348 - 2 CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]				P						
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac in Adult and Pediatric

Prescription Use Only Per 21 CFR 801 Part  
 D Concurrence of CDRH



# 7348 - 5 CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

Prescription Use Only Per 21 CFR 801 Part  
D Concurrence of CDRH

# 7348 - HFCW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping [3]	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Petal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular				P						
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k110688

- [1] Small Organs includes Breast, Thyroid and Testicles  
[2] Cardiac is Adult and Pediatric

Prescription Use Only Per 21 CFR 801 Part  
D Concurrence of CDRH

# 7348 - EC1123

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal	P	P	P		P	P	P		P	
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal	P	P	P		P	P	P		P	
Transvaginal	P	P	P		P	P	P		P	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urologic <sup>4</sup> )	P	P	P		P	P	P		P	

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k132231

[1] Small Organ includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Combined modes are: B + M + PW + CFM + PD

Prescription Use Only Per 21 CFR 801  
Part D Concurrence of CDRH

# 7348 - IOE323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWI	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P			
Intraoperative (Abdominal)	P	P	P		P	P	P			
Intraoperative Neurological										
Pediatric	P	P	P		P	P	P			
Small Organ [1]	P	P	P		P	P	P			
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular	P	P	P		P	P	P			
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)	P	P	P		P	P	P			
Musculo-skeletal Superficial (including Nerve Blocking)	P	P	P		P	P	P			
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CFM + PD

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH

# 7348 - LP323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (HEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal	P	P	P		P	P	P			
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic	P	P	P		P	P	P			
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E  
Previously cleared via k121364

- [1] Small Organs includes Breast, Thyroid and Testicles  
[2] Cardiac in Adult and Pediatric  
[3] Combined modes are: B + M + PW + CFM + PD

Prescription Use Only Per 21 CFR 801  
Part D Concurrence of CDRH

# 7348 - TEE132

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (CFM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	N	P	
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CW + CFM + PD

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH

# 7348 - TEE022

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	Mode of Operations									
	B	M	PW(1)	CW(1)	Color Doppler	Amplitude Doppler	Combined [3]	Tissue Velocity Mapping (TVM)	Harmonic Imaging (TEI)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric										
Small Organ [1]										
Neonatal Cephalic										
Adult Cephalic										
Cardiac [2]										
Transesophageal (Cardiac)	P	P	P	P	P	P	P	N	P	
Transesophageal (Non Cardiac)										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional (including Nerve Blocking)										
Musculo-skeletal Superficial (including Nerve Blocking)										
Other (Urological)										

N: New indication; P: Previously cleared by FDA; E: Added under Appendix E

Previously cleared via k121384

- [1] Small Organs includes Breast, Thyroid and Testicles  
 [2] Cardiac is Adult and Pediatric  
 [3] Combined modes are: B + M + PW + CW + CFM + PD

Prescription Use Only Per 21 CFR 801  
 Part D Concurrence of CDRH